IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: ALFUZOSIN HYDROCHLORIDE PATENT LITIGATION	)	MDL Docket No. 08-md-1941 GMS

MEMORANDUM OPINION

I. INTRODUCTION

In this consolidated patent infringement action, the plaintiffs, sanofi-aventis and sanofi-aventis U.S. LLC (collectively "sanofi-aventis") allege that the defendant, Mylan Pharmaceuticals Inc.'s ("Mylan") proposed generic alfuzosin hydrochloride product infringes the asserted claims of U.S. Patent No. 4,661,491 (the "'491 patent"). The court held a four-day bench trial in this matter on May 3 through May 6, 2010.[1] At the close of the evidence, the court issued an oral ruling finding that the '491 patent was not invalid as obvious. The court advised the parties that it would issue more detailed findings of fact and conclusions of law, which are set forth below. In summary, pursuant to Fed. R. Civ. P. 52(a), and after having considered the record in this case and the applicable law, the court concludes that: (1) the '491 patent is not invalid; and (2) an award for attorneys' fees and costs is not warranted in this case.[2]

[1] On May 4, 2010, the court issued an oral ruling from the bench finding that the plaintiffs had proven by a preponderance of evidence that Mylan's proposed generic alfuzosin hydrochloride product will infringe the asserted claims of the '491 patent. The court further found that Mylan will induce infringement of the '491 patent.

[2] The court makes these findings based on substantial evidence in the record and after hearing the trial testimony first hand. Because the court had the benefit of observing witness demeanor in the courtroom, it was possible to make credibility determinations that aided the court in resolving conflicting testimonial evidence and, in part, in determining which evidence to credit and which evidence to discredit.

II. FINDINGS OF FACT

The court makes the following factual findings:

A. The '491 Patent and Procedural Background

1. This is a patent infringement action in which the plaintiffs contend that Mylan's proposed 10 mg alfuzosin hydrochloride product infringes the asserted claims of the '491 patent.

2. The application that led to the '491 patent was filed on May 27, 1986. The '491 patent claims priority from a foreign application filed in France on May 28, 1985.

3. The '491 patent was issued by the USPTO on April 28, 1987, to Synthelabo, a predecessor sanofi-aventis. Synthelabo was the named assignee of the named inventor of the '491 patent, François Regnier. Sanofi-aventis is the owner of the entire right, title, and interest in the '491 patent.

4. The '491 patent claims a method for treating humans for dysuria by administering an effective non-toxic amount of alfuzosin or a pharmaceutically acceptable salt thereof.

5. Alfuzosin is an $alpha_1$-blocker that relaxes the smooth muscle in the lower urinary tract, including the bladder neck and prostate, resulting in an improvement in urine flow and a reduction in the symptoms of benign prostatic hypertrophy or benign prostatic hyperplasia ("BPH"). Alfuzosin hydrochloride is a pharmaceutically acceptable salt of alfuzosin.

6. The '491 patent is subject to a term extension of 1,697 days, pursuant to 35 U.S.C. § 156, and is set to expire on January 18, 2011.

7. Sanofi-aventis holds an approved NDA No. 21-287 on Uroxatral® brand alfuzosin hydrochloride extended-release tablets, and is the exclusive distributor of Uroxatral® in the United States.

8. The '491 patent is listed in the FDA's Orange Book in connection with sanofi-aventis' Uroxatral® extended-release tablets.

9. On June 12, 2007, Mylan submitted an ANDA No. 79-014 to the FDA seeking approval to engage in the commercial manufacture, use and/or sale of a 10 mg extended release generic Uroxatral® product. Mylan's ANDA names Uroxatral® as the reference listed drug.

10. On August 27, 2007, sanofi-aventis received a Paragraph IV Certification letter from Mylan notifying it that Mylan's ANDA includes a certification that the '491 patent is invalid, unenforceable, or will not be infringed by the commercial, manufacture, use or sale of the drug product described in Mylan's ANDA.

11. On September 21, 2007, sanofi-aventis filed its action for patent infringement against Mylan.

12. On June 9, 2008, this action was consolidated for pretrial proceedings with other related suits by the Judicial Panel on Multidistrict Litigation.

B. The Scientific Background

The court will only briefly discuss the prostate and BPH, as it concludes that the facts regarding the prostate, its location, and BPH are not in dispute.

13. The prostate is a gland located below the bladder in men. It is an integral part of the male reproductive system and is also related to the act of urination.

14. As men age, the prostate often becomes enlarged, a condition known as BPH.

15. About half of men with BPH will experience bothersome urinary symptoms, including urinary frequency, nocturia (waking up to urinate at night), poor urine flow, hesitancy, incomplete emptying, straining, and painful urination. These symptoms are often referred to as

lower urinary tract symptoms ("LUTS"), and are traditionally classified as irritative or obstructive. Irritative symptoms include frequency, urgency and nocturia, while obstructive symptoms include hesitancy, poor urine flow, incomplete emptying and straining.

16. Most men that experience bothersome LUTS find the irritative symptoms more troublesome than the obstructive symptoms.

C. Treatments

17. In 1985, a surgical treatment known as transurethral resection of the prostate ("TURP") was the primary treatment option for patients with BPH. The procedure involved introduction of a resectoscope through the penile urethra to mechanically remove portions of the prostate obstructing the urethra by way of electrocauterization.

18. Two other surgical procedures were available in 1985, namely transurethral incision of the bladder neck and open prostatectomy, but they were not as widely used as TURP.

19. Many men experiencing bothersome LUTS due to BPH elected not to undergo surgical treatment due to the potential adverse side effects from the surgery, the increased risks associated with anesthesia due to advanced age, and co-morbidities.

20. In 1985, the FDA had not approved any pharmaceutical treatments for the symptoms of BPH.

21. During this time, persons of ordinary skill in the art began searching for well-tolerated and effective pharmaceutical therapies to treat the symptoms of BPH as an alternative to

surgery. Among the approaches being investigated were hormonal therapy[3] and alpha-blockers.[4]

D. Alpha-Blockers

22. The body contains adrenergic receptors, or proteins associated with the cell surfaces of tissues, which are classified into various alpha-receptor and beta-receptor categories.

23. Alpha-receptors are further divided into two subsets, $alpha_1$-receptors and $alpha_2$-receptors. The prostate contains an abundance of both $alpha_1$- and $alpha_2$-receptors.

24. Nonselective alpha-blockers, such as phenoxybenzamine, block both $alpha_1$- and $alpha_2$-receptors. Selective alpha-blockers, such as prazosin and alfuzosin, bind to a specific type of receptor; for example, $alpha_1$-blockers bind to $alpha_1$ receptors.

25. Prior to May 28, 1985, persons of ordinary skill in the art studied the effects of phenoxybenzamine and prazosin on the symptoms of BPH.

26. Prior to May 28, 1985, no one had used or suggested the use of alfuzosin for the treatment of dysuria or dysuria of BPH.

III. CONCLUSIONS OF LAW

The court makes the following conclusions of law.

A. Legal Standards

27. A patent is presumed valid. 35 U.S.C. § 282. "Each claim of a patent . . . shall be presumed valid independently of the validity of other claims . . . ." *Id.*

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[3] The court will not discuss hormonal therapy because it has no bearing on this opinion.

[4] The FDA first approved pharmaceuticals to treat symptomatic BPH in the United States in 1992. The FDA approved the first alpha-blocker to treat symptomatic BPH in 1993.

28. 35 U.S.C. § 103(a) provides that a patent may not be obtained "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious to a person having ordinary skill in the art."

29. "The presumption of validity is a procedural device that mandates that the party asserting invalidity bears the initial burden of establishing a *prima facie* case of obviousness under 35 U.S.C. § 103. Once a *prima facie* case of obviousness has been established, the burden shifts to the patentee to go forward with rebuttal evidence showing facts supporting nonobviousness. The party asserting invalidity, however, always retains the burden of persuasion on the issue of obviousness until a final judgment is rendered." *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 291-92 (Fed. Cir. 1985) (internal citations omitted).

30. Obviousness is a question of law that is predicated upon several factual inquiries. *Richardson-Vicks v. Upjohn Co.*, 122 F.3d 1476, 1479 (Fed. Cir. 1997). Specifically, the trier of fact must consider four issues: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed subject matter and the prior art; and (4) secondary considerations of non-obviousness, such as commercial success, long felt but unsolved need, failure of others, acquiescence of others in the industry that the patent is valid, and unexpected results. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).

31. A party seeking to challenge the validity of a patent based on obviousness must also demonstrate by "clear and convincing evidence" that the invention described in the patent would have been obvious to a person of ordinary skill in the art at the time the invention was made.[5] *Pfizer,*

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[5] "Clear and convincing evidence is evidence that places in the fact finder 'an abiding conviction that the truth of [the] factual contentions are 'highly probable.'" *Alza Corp. v. Andrx Pharms., LLC*, 607 F. Supp. 2d 614, 631 (D. Del. 2009) (quoting *Colorado v. New Mexico*, 467 U.S. 310, 316

Inc. v. Apotex, Inc., 480 F.3d 1348, 1359-60 (Fed. Cir. 2007). However, in determining what would have been obvious to one of ordinary skill in the art at the time of invention, the use of hindsight is not permitted. *See KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 421, 127 S. Ct. 1727, 1742, 167 L. Ed. 2d 705, 724 (2007) (cautioning against "the distortion caused by *hindsight bias*" and "arguments reliant upon *ex post reasoning*" in determining obviousness) (emphasis added).

32. In *KSR*, the Supreme Court rejected a rigid application of the principle that there should be an explicit "teaching, suggestion, or motivation" in the prior art, the nature of the problem, or the knowledge of a person having ordinary skill in the art, in order to find obviousness. *See KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. at 415. The *KSR* Court acknowledged, however, the importance of identifying "'a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does' in an obviousness determination." *Takeda Chem. Indus. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356-57 (Fed. Cir. 2007) (quoting *KSR*, 550 U.S. at 418).

B. The Person of Ordinary Skill in the Art

33. As of May 28, 1985, a person with an ordinary level of skill in the art to which the '491 patent pertains would have a Doctor of Medicine degree or a degree in pharmacology, and exposure to clinical treatment of BPH.

C. The Scope and Content of the Prior Art

34. Mylan has asserted three pieces of prior art in its affirmative case on obviousness against the '491 patent: (1) P. Guinebault et al., *Absolute Bioavailability of Alfuzosine, A New α1-Post Synaptic Receptor Antagonist, After Oral and Intravenous Administration*, Biopharmaceutics

(1984)).

and Pharmacokinetics, 2 Eur. Congr. 578 (1984) (the "Guinebault reference"); (2) H. Hedlund et al., *Effects of Prazosin in Patients with Benign Prostatic Obstruction*, 130 J. Urol. 275 (1983) (the "Hedlund reference"); and (3) Herbert Lepor & Ellen Shapiro, *Characterization of Alpha1 Adrenergic Receptors in Human Benign Prostatic Hyperplasia*, 132 J. Urol. 1226 (1984) (the "Lepor reference").

35. Mylan does not assert that any of the three pieces of prior art standing alone renders the '491 patent obvious. Rather, Mylan contends that it is the combination of the Guinebault, Hedlund, and Lepor references that renders the '491 patent obvious. More specifically, Mylan argues that: (1) the Guinebault reference teaches that alfuzosin was safe and effective for use in humans; (2) the Hedlund reference teaches that selective alpha$_1$-blockers, like prazosin, can be used safely and effectively to treat symptoms of BPH; and (3) the Lepor reference discloses the identification and characterization of alpha$_1$-adrenergic receptors in the prostate, thus confirming the presence of alpha$_1$-adrenergic receptors in the human prostate. Therefore, Mylan argues that the claims of the '491 patent would have been obvious to a person of ordinary skill in the art prior to May 28, 1985, in view of the Guinebault reference when combined with the Hedlund and Lepor references.

36. None of the three prior art references cited by Mylan disclose the use of alfuzosin for treatment of dysuria or dysuria of BPH. (Tr. at 422:1-4.) Nor do the three prior art references disclose the use of alfuzosin to treat any disorder or disease.

37. The Guinebault reference studied the definition of the pharmacokinetic parameters of alfuzosin after intravenous administration and of its absolute bioavailability. (DTX-0051 at 578.) The authors noted that alfuzosin, a new alpha$_1$-receptor antagonist, was undergoing phase III clinical

trials in several European countries. (Id.) The results of the study indicated that 5 to 40 mg doses of alfuzosin exhibit linear pharmacokinetics; that is, that the levels of alfuzosin in the blood increased linearly as the dose increased. (Id. at 582.)

38. In the Hedlund reference, the authors used prazosin, a selective alpha$_1$-blocker in a double-blind crossover study in 20 men with BPH. (DTX-0052 at 275.) The study reported that treatment with prazosin resulted in improved urinary flow and bladder evacuation, as well as a significant decrease in obstructive symptoms with virtually no side effects. (Id. at 276.) The study further reported, however, that irritative symptoms, such as frequency, urgency, and nocturia were not reduced by prazosin, and that the failing effect of prazosin differs from the results obtained with a non-selective alpha-blocker phenoxybenzamine. (Id.) The study concluded that "prazosin seems to be an effective therapeutic alternative in patients with [BPH]." (Id.)

39. In the Lepor reference, the authors identified and characterized alpha$_1$ adrenergic receptors in the prostate using radioligand receptor binding methods. (DTX-0053 at 1226.) The reference reported that "[t]he characterization of the alpha$_1$ adrenergic receptor in the human prostate provides the foundation for further critical investigation of the etiology and pharmacologic management of urinary obstruction in men with BPH." (Id. at 1229.) The reference cautioned, however, that "[t]he role of prostatic alpha adrenergic receptors in mediating prostatic urethral resistance cannot be unequivocally inferred from our binding studies since the localization of the alpha1 receptors in the various compartments of the prostate remains unknown." (Id.)

D. Obviousness Discussion

40. Having considered the scope and content of the prior art, the court concludes that there is substantial evidence in the record that supports the conclusion that one of ordinary skill in

the art as of May 28, 1985 would not have been motivated to combine the Guinebault, Hedlund , and Lepor references. Moreover, the cited references in combination would not teach a person of ordinary skill in the art that alfuzosin would be safe and effective in the treatment of the symptoms of dysuria or dysuria of BPH. Indeed, only one of the cited references, the Guinebault reference, studies alfuzosin and that study is, as sanofi-aventis' expert, Dr. Lepor, testified, "simply a pharmakokinetic study." (Trial Tr. at 175:10-11.) Further, as Dr. Lepor testified, the Guinebault reference does not teach anything about alfuzosin's effectiveness or safety in treating any condition, does not measure any pharmacologic effect, discusses only administering one dose to the eight volunteers, and does not disclose any indications for alfuzosin. (Id. at 175:19-176:11; 195:15-20.) The Guinebault reference teaches nothing about clinical utility (id. at 201:23-24), or about the amount of alfuzosin that would be required to antagonize an $alpha_1$-receptor (id. at 129:5-8; 448:10-12). Thus, the Guinebault reference would not teach a person of ordinary skill in the art in May 1985 that alfuzosin is safe and effective for use in humans for the treatment of dysuria or dysuria in men having BPH.

41. Next, while the Hedlund reference teaches that treating patients with prazosin resulted in improved urinary flow and decreased obstructive symptoms,[6] it also teaches that prazosin was not effective at treating irritative symptoms of BPH. According to Dr. Lepor, a person of ordinary skill in the art would look at the Hedlund reference and conclude that prazosin is no better than placebo at treating the most troublesome symptoms of BPH i.e., the irritative symptoms; in fact, it is worse. (Id. at 181:10-13; 183:17-20.) Thus, Dr. Lepor "would be disenfranchised with prazosin

[6] Dr. Lepor testified, and the court is persuaded, that "obstruction is not synonymous with obstructive symptoms, which is not synonymous with dysuria secondary to BPH." (Tr. at 189:11-13.)

as a treatment" for dysuria of BPH. (Id. at 183:21-22.) In other words, Hedlund would teach away from treating BPH with prazosin and from pursuing alpha$_1$-blockers as a treatment option for dysuria or dysuria of BPH. (Id. at 196:6-8.) Dr. Lepor also testified that the Hedlund reference would not have been reliable to a person of ordinary skill in the art, because it does not show any statistical comparison between placebo and prazosin for irritative symptoms, obstructive symptoms or total symptoms, and the study was conducted on too small a group – 20 subjects. (Id. at183:1-7; 185:25-186:9.) Thus, based on the disclosure of the Hedlund reference, a person of ordinary skill in the art could not say that prazosin performed better than placebo, or that prazosin or any other alpha$_1$-blocker would treat dysuria with any reasonable expectation of success.[7] (Id. at 189:16-190:8.)

42. With respect to the Lepor reference, the court agrees with Mylan that the authors identified and confirmed the presence of alpha$_1$-adrenergic receptors in the human prostate. The Lepor reference, however, does not disclose the location of the alpha$_1$ adrenergic receptors or their functionality, i.e. whether they play any role in mediating prostatic urethral resistance. (Tr. at 192:1-4; see id. at 130:19-22; 450:18-21.) Nor does it disclose the use of alpha$_1$-blockers to treat dysuria or dysuria of BPH. (Tr. at 192:11-16; see id. at 451:20-452:1.) Indeed, the authors concluded that their work provided a foundation for further clinical investigation into the relationship between alpha$_1$-receptors and pharmaceutical treatment of BPH. (DTX-0053 at 1229.) They further concluded that "[t]he role of prostatic alpha adrenergic receptors in mediating prostatic urethral resistance cannot be unequivocally inferred from our binding studies since the localization of the alpha$_1$ receptors in the various compartments of the prostate remains unknown." (Id.) As Dr. Lepor

[7] An article that Mylan's expert, Dr. Andriole, published in 2006 supports this conclusion. The article states that a 1987 paper by Kirby was the *first* to show efficacy of an alpha$_1$-blocker in BPH therapy. (Tr. at 123:1-124:16; see PTX-249 at n. 13) (emphasis added).

testified, just because he knows that receptors are present, he cannot talk about the function of the receptors until he has functional data, and he cannot talk about prostatic resistance until he measures it. (Tr. at 193:1-5.) Thus, the Lepor reference simply taught a person of ordinary skill in the art that alpha$_1$-receptors were present in the prostate.

43. Finally, the court concludes that the combination of the Guinebault, Hedlund, and Lepor references would not have taught a person of ordinary skill in the art as of May 28, 1985 the inventions claimed in the '491 patent, because the references do not disclose: (1) that alfuzosin, or any other alpha1-blocker, could treat dysuria,[8] (2) the effective amount of alfuzosin that could be used in treating any condition, including dysuria; and (3) that alfuzosin could safely treat any condition, including dysuria.[9] Nor could the combination of the asserted references teach a person of ordinary skill in the art about the safety and efficacy of using alfuzosin to treat dysuria or dysuria of BPH because, as Dr. Lepor, Dr. Bruskewitz, and Dr. Andriole testified, the only way one can know whether a selective alpha$_1$-blocker is safe and effective is to conduct clinical trials. (Id. at 134-138; 144:16-145:4; 172:24-173:4; 173:9-11; 200:17-19; 456:17-20; 462:8-463:2; 464:3-16.)

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[8] Indeed, Mylan's expert, Dr. Bruskewitz, testified that, as late as 1991, he believed that the effects of alpha blockage on BPH were modest, he did not discuss alfuzosin as an alpha-blocker in his publications, and the notion of a younger, healthy male with BPH going on an alpha blocking drug for many years was probably not appealing to most physicians and patients. (Tr. at 434:1-435:2; see PTX-267.)

[9] Both Dr. Andriole and Dr. Bruskewitz testified that they had neither treated anyone with alfuzosin nor suggested that anyone use alfuzosin to treat dysuria or dysuria of BPH. (Tr. at 113:6-19; 424:21-24.) They also testified that they were not aware of anyone using alfuzosin to treat dysuria or dysuria of BPH prior to May 28, 1985. (Id. at 113:9-11; 424:25-425:3.) Further, Dr. Bruskewitz testified that in 1985 persons of ordinary skill in the art would have concerns about the safety and proven efficacy in seeking treatments for BPH. (Id. at 437:7-10.)

44. Moreover, in the case of alfuzosin, one might have predicted that it would not be safe and effective, because prazosin had noticeable side effects and did not treat the irritative symptoms of BPH. (Tr. at 200:20-201:9.) Thus, a person of ordinary skill in the art as of May 28, 1985 would not have had a reasonable expectation that alfuzosin would treat dysuria or dysuria of BPH based on the combined teachings of the Guinebault, Hedlund, and Lepor references.

E. Secondary Considerations of Non-obviousness

45. There is substantial evidence in the record of several relevant secondary considerations that further support a finding of non-obviousness. *See Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983) (noting that "evidence of secondary considerations may often be the most probative and cogent evidence in the record"). Specifically, sanofi-aventis presented both expert testimony and documentary evidence chronicling: (1) the long-felt need in the field of urology and the market at the time for a pharmaceutical treatment for dysuria and dysuria of BPH; (2) others' efforts to develop and market an effective pharmaceutical treatment for dysuria and dysuria of BPH; (3) the unexpected efficacy and pharmacology, and favorable side effect profile of alfuzosin in treating dysuria and dysuria of BPH; (4) the commercial success of Uroxatral®; and (5) the nexus between the commercial success and the claimed invention. (Trial Tr. at 113:2-114:2; 127:1-128:4; 199-201; 428:3-16; 430-32; 456:21-25; 484-501; 594-95; 626:8-627:19; 730:4-6; 734:3-735:4; 737-40; 747-48.)

46. For example, on the issue of commercial success, it is undisputed that in 2009 Uroxatral® had sales of approximately $228 million, and that total sales of Uroxatral® since its introduction into the market in 2003 have exceeded $790 million. (Id. at 601:5-9; 17.) It is also undisputed that there were a total of 1.8 million prescriptions for Uroxatral® in 2009, which includes

approximately 590,000 new prescriptions. (Id. at 603:9-606:1; 622:18-25.) Finally, it is undisputed that Uroxatral® sales have grown every year since its launch, when generic alpha-blockers were introduced into the market. (Id. at 601:12-603:7; 612:8-25; 701:10-12; 704:3-15.) Accordingly, the court, finds that the relevant secondary considerations support the conclusion that the '491 patent is not invalid as obvious over the prior art.

47. In sum, the court is not persuaded that the defendants have established by clear and convincing evidence that the '491 patent is obvious in light of the prior art. The court finds that there are significant differences between the prior art and the claimed inventions, such that a person of ordinary skill in the art would not have been motivated to combine the Hedlund, Lepor, and Guinebault references. In addition, there exist a number of secondary considerations that severely undermine the defendant's claims of obviousness. Accordingly, the court concludes that the '491 patent is not invalid as obvious under 35 U.S.C. § 103.

F. Attorneys' Fees and Costs

48. Because the court does not find this case to be exceptional by clear and convincing evidence as required by 35 U.S.C. § 285, the court will not award attorneys' fees and costs.

49. In deciding whether to award attorney's fees, the court must undertake a two-step inquiry. *Interspiro USA, Inc. v. Figgie Intern. Inc.*, 18 F.3d 927, 933 (Fed. Cir. 1994). First, the court "must determine whether there is clear and convincing evidence that the case is 'exceptional.'" *Id.* (quotation omitted). Second, the court must determine whether "an award of attorney fees to the prevailing party is warranted." *Id.* Exceptional cases include: "inequitable conduct before the PTO; litigation misconduct; vexatious, unjustified, and otherwise bad faith litigation; a frivolous suit or

willful infringement." *Epcon Gas Sys., Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1034 (Fed. Cir. 2002) (citation omitted).

50. An award of attorney fees under § 285 is not intended to be an "ordinary thing in patent cases," and should be limited to circumstances in which it is necessary to prevent "a gross injustice" or bad faith litigation. *Forest Labs., Inc. v. Abbott Labs.*, 339 F.3d 1324, 1329 (Fed. Cir. 2003); *see also Aptix Corp. v. Quickturn Design Sys., Inc.*, 269 F.3d 1369, 1375 (Fed. Cir. 2001) (affirming an award of attorney fees under § 285 for the "extreme litigation misconduct" of falsifying evidence); *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547 (Fed. Cir. 1989) (affirming an award under § 285 following repeated violations of a permanent injunction and a district court finding of a "strategy of vexatious activity").

51. Mylan's conduct in this case does not rise to a level of bad faith or vexatious litigation that warrants an award of attorneys' fees and costs. Indeed, the record demonstrates that throughout this litigation, both sides vigorously, and in apparent good faith, defended their respective positions. *See Forest Labs., Inc. v. Ivax Pharms., Inc.*, No. 03-891-JJF, 2008 U.S. Dist. LEXIS 14623, at *6-7 (D. Del. Feb. 26, 2008) (noting that "hard-fought" litigation does not necessarily constitute "vexatious or bad faith litigation" for purposes of awarding attorney fees under § 285). The court therefore finds that none of the parties are entitled to an award for attorneys' fees and costs in this case.

Dated: May 14, 2010

CHIEF, UNITED STATES DISTRICT JUDGE